

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMP

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Certifier	J. W. Wadsworth

[Docket No. 99N-2674]

Jay Marcus; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Mr. Jay Marcus for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On October 21, 1994, the U.S. District Court for the District of Maryland accepted Mr. Marcus' plea of guilty to one count of conspiracy to defraud the United States under 18 U.S.C. 371 and sentenced Mr. Marcus for the crime.

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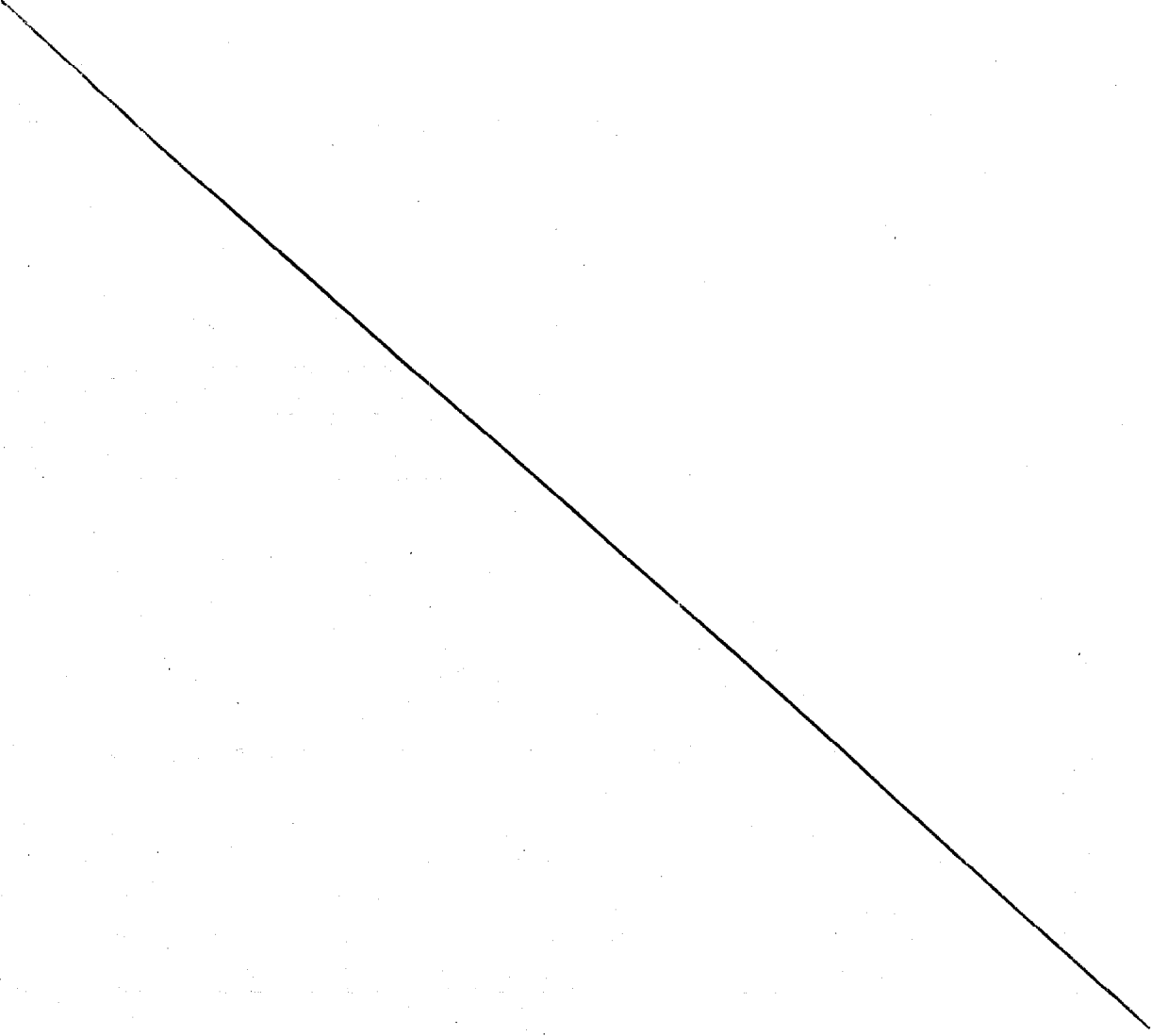
As a result of this conviction, FDA published in the **Federal Register** of October 15, 1999 (64 FR 55944), a proposal to debar Mr. Marcus for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Marcus an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i) of the act (21 U.S.C. 355a(b)(2)(B)(i)), that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus was provided 30 days to file objections and request a hearing. Mr. Marcus did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(b)(2)(B)(i) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Jay Marcus has been convicted of a felony under Federal law for conspiracy to defraud the United States.

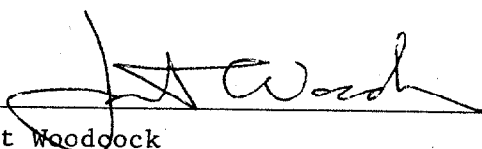
As a result of the foregoing finding, Mr. Jay Marcus is debarred for a period of 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [insert date of publication in the **Federal Register**] (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Marcus in any capacity during his period of debarment, will be subject to civil money penalties. If Mr. Marcus, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Marcus during his period of debarment.

Any application by Mr. Marcus for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 99N-2674 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of



information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/11/00
September 11, 2000

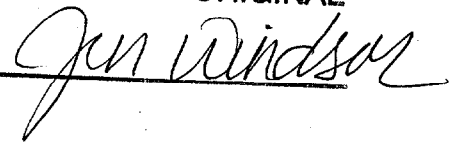


Janet Woodcock
Director,
Center for Drug Evaluation and Research

[FR Doc. 00-???? FILED ?? ?? 00; 8:45 AM]

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Jen Windsor